APEC-USC Training Program

"Medical Devices 2021: Regulatory Harmonization of Clinical and Non-Clinical Development"

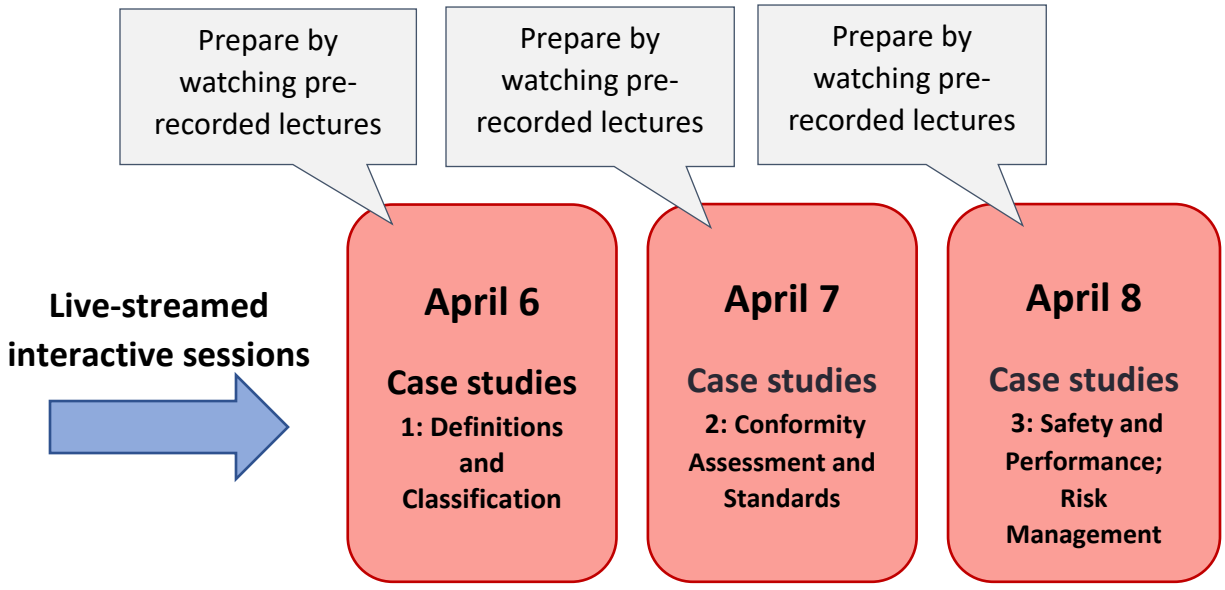
April 6-9, 2021

Background

Dissonant international regulations can impede trade and access to medical products. APEC's Regulatory Harmonization Steering Committee (RHSC) is attempting to assist the convergence of regulatory approaches for medical devices through training programs that can expand your knowledge of harmonized guidances from ICH (for drugs) and IMDRF/GHTF (for devices). The training programs offered by the APEC-USC Center of Excellence are designed to increase understanding of GHTF/IMDRF documents that support non-clinical and clinical device development. In these programs we will discuss the content and application of certain key documents that are provided as background material.

The coursework has two parts:

Part 1 will start when you register and begin to watch a set of pre-recorded lectures. These will take about 5 hours to review. They will prepare you to attend three 90-minute, interactive class sessions over Zoom, where experts will discuss interesting case studies that give insight into the application of the harmonized guidances. Each day will include a short online test so that you can test your knowledge before and after each session. (Certification is **not** dependent on your test scores)



Part 2 will focus on three new IMDRF documents that focus on clinical development. Experts will present a one-day symposium on **April 9** in collaboration with the USC Southern California Clinical and Translational Science Institute, that will be streamed live using the Zoom platform. You will learn how these documents act as a foundation for medical device studies and compliment ISO 14155v:2020, "Clinical investigation of medical devices for human subjects — Good clinical practice". If you are in a time zone that makes real-time attendance difficult, lectures will be recorded and archived so that you can view the content at your convenience.

Preparing for the Program

You can talk to us if you need more information before you register; no fee is charged for regulators. See contact information below. I am happy to help you decide whether this training program is for you! You can take either part of the program and will receive a certificate after participating in each part. After you register, you will receive a private link to access the lectures, live streams, training resources and other instructions.

Contacts

Dr. Frances Richmond,
Director, DK Kim International Center for Regulatory Science,
University of Southern California, USA
fjr@usc.edu
Phone: 1+ 323-442-3531

Ms. Debbie Shroyer,
Program Assistant, DK Kim International Center for Regulatory Science,
University of Southern California, USA
schroyer@usc.edu
Phone: 1+ 323-442-3521